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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/866,793	05/30/2001	Stephen Joseph Vesper	VESPER1	5682

1444 7590 02/01/2010

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EXAMINER	
DUFFY, PATRICIA ANN	

ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
02/01/2010	PAPER

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte STEPHEN JOSEPH VESPER

Appeal 2009-006220[1]
Application 09/866,793
Technology Center 1600

Decided:[2] February 1, 2010

Before TONI R. SCHEINER, DEMETRA J. MILLS, and
FRANCISCO C. PRATS, *Administrative Patent Judges*.

PRATS, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal under 35 U.S.C. § 134 involves claims to methods for determining if an animal has been exposed to a hemolysin-producing fungus.

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[1] The United States Environmental Protection Agency is the real party in interest (App. Br. 1 (entered August 11, 2008)).
[2] Oral argument was presented in this case on January 14, 2010.

The Examiner rejected the claims as anticipated, obvious, lacking adequate written description, lacking enablement, and being indefinite. We have jurisdiction under 35 U.S.C. § 6(b).

We reverse the Examiner's rejections for anticipation, enablement, and indefiniteness, but affirm the obviousness and written description rejections.

STATEMENT OF THE CASE

"Hemolysins are molecules that are designated as such because they have the ability to lyse red blood cells (RBC). It is now recognized that the biological significance of these toxins goes beyond their lysis of RBC to their more general ability to form pores in many cells" (Spec. [0008]).

Claims 23-33 are pending and on appeal (App. Br. 3).[3] Claims 23, 30, and 33 are representative and read as follows:

> 23. A method for determining if an animal has been exposed to a specific hemolysin-producing fungus, which hemolysin is species-specific, comprising:
>
> a. contacting a sample from said animal with labeled antibodies which bind to the hemolysin produced by the fungus or to active fragments of the hemolysin; and
>
> b. detecting any complex formed between the labeled antibodies and the hemolysin or active fragments thereof.
>
> 30. A method for determining if a building contains a hemolysin-producing fungus comprising:
>
> a. obtaining a sample from the building;
>
> b. obtaining hemolysin from the sample if hemolysin-producing fungi are present in the sample;
>
> c. contacting the sample with labeled antibodies which bind to the fungal hemolysin or to active fragments of the fungal hemolysin; and

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[3] Appeal Brief entered August 11, 2008.

d. detecting any complex formed between the labeled antibodies and the fungal hemolysin or active fragments thereof.

33. A method for determining if an animal has been exposed to a specific hemolysin-producing fungus comprising detecting the presence of the hemolysin produced by the fungus in a sample from the animal, the presence of the hemolysin in the sample indicating that the animal has been exposed to the hemolysin-producing fungus.

The Examiner cites the following documents as evidence of unpatentability:

Berg US 6,210,670 B1 Apr. 3, 2001

Moïse Bendayan, *Possibilities of False Immunocytochemical Results Generated by The Use of Monoclonal Antibodies: The Example of the Anti-proinsulin Antibody*, 43 J. HISTOCHEM. AND CYTOCHEM. 881-886 (1995).

Kenneth L. Bost and David W. Pascual, *ANTIBODIES AGAINST A PEPTIDE SEQUENCE WITHIN THE HIV ENVELOPE PROTEIN CROSSREACTS WITH HUMAN INTERLEUKIN-2*, 17 IMMUNOLOGICAL INVESTIGATIONS 577-586 (1988).

Keiichi Ebina et al., *ROLE OF ASP-HEMOLYSIN ON EXPERIMENTAL ASPERGILLUS INFECTION FOR MICE*, 35 JAPANESE JOURNAL OF MEDICAL SCIENCE AND BIOLOGY 140-141 (1982).

Keiichi Ebina et al., *ASP-HEMOLYSIN SIGNIFICANCE AS A VIRULENCE FACTOR WITH BIOLOGICAL ACTIVITIES FROM ASPERGILLUS FUMIGATUS*, 38 JAPANESE JOURNAL OF MEDICAL MYCOLOGY 155-160 (1997) (as translated, hereinafter "Ebina '97").

Ed Harlow and David Lane, ANTIBODIES A LABORATORY MANUAL, Cold Spring Harbor Press Inc., pp. 390-393 (1988).

Osamu Sakaguchi et al., *ROLE AND BIOLOGICAL ACTIVITY OF HEMOLYTIC TOXIN ON ASPERGILLUS INFECTIONS*, 25 JAPANESE JOURNAL OF MEDICAL MYCOLOGY, 219-224 (1984) (as translated).

Toshihiko Watanabe et al., *HOMOLYTIC ACTIVITY OF HUMAN RED BLOOD CELLS BY CANDIADA SPECIES,* 46 JOURNAL OF TOHOKU UNIVERSITY OF PHARMACOLOGY 145-148 (1999) (as translated).

Katsushi Yokota et al, *Studies on the Toxin of Aspergillus fumigatus -- VII. Purification and Some Properties of Hemolytic Toxin (Asp-Hemolysin) from Culture Filtrates and Mycelia*, 21 MICROBIOLOGY IMMUNOLOGY 11-22 (1977).

The following rejections are before us for review:

(1) Claims 23 and 25-29, rejected under 35 U.S.C. § 103(a) as obvious in view of Sakaguchi and Harlow (Ans. 4-5);[4]

(2) Claim 33, under 35 U.S.C. § 102(b) as anticipated by Sakaguchi (Ans. 5-7);

(3) Claims 23-29 and 33, rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement (Ans. 7);

(4) Claims 30-32, rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement (Ans. 7-8);

(5) Claims 30-32, rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement (Ans. 8-9);

(6) Claims 23-26, rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement (Ans. 9-10); and

(7) Claims 30-32, rejected under 35 U.S.C. § 112, second paragraph, as being indefinite (Ans. 10-11).

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[4] Examiner's Answer mailed November 17, 2006.

OBVIOUSNESS

ISSUE

The Examiner cites Sakaguchi as disclosing the antibody-based detection of Asp-hemolysin "in tissues . . . from a mouse infected with *Aspergillus fumigatus*" (Ans. 4). The Examiner finds that Sakaguchi differs from the claims in that Sakaguchi detects antibody-to-hemolysin binding "by labeling the second or indirect antibody, rather than the primary or binding antibody" (*id.* at 5).

To meet that limitation, the Examiner cites Harlow as disclosing that "labeling of the primary or binding antibody provides for the advantage of cleaner signals with lower background" (*id.*). Based on these teachings the Examiner concludes that it would have been obvious to label the primary antibody used Sakaguchi's hemolysin-detecting method as recited in the claims (*id.*).

Appellant contends that the claims are directed to assaying for specific hemolysin-producing fungi, and that a person skilled in the art "need not be told *in haec verba* that each fungus produces a unique hemolysin, because it is inherent that the hemolysins are unique if one is able to identify different strains of fungi, which is one object of the present invention" (App. Br. 8). In contrast, Appellant urges, the "Examiner appears to be confusing antibody specificity with hemolysin specificity" (*id.*).

Moreover, Appellant argues, the preamble of claim 23 requires the practitioner to determine *if* an animal has been exposed to a hemolysin-producing fungus (*id.* at 9). In contrast, Appellant urges, Sakaguchi already knew that the mouse had been infected with the fungus, as Sakaguchi had

purposely infected the mouse with the fungus to study the progress of the infection and tissues involved (*id.* at 9-10; *see also* Reply Br. 2-3).[5]

The Examiner responds that the structure of the *Aspergillus fumigatus* hemolysin was known in the art (Ans. 11 (citing Ebina '97)). Moreover, the Examiner argues, Sakaguchi "indicates that exposure to a hemolysin producing strain of *Aspergillus fumigatus* could be and was detected in experimental infection by detection of asp-hemolysin from *Aspergillus fumigatus* in tissue samples using antibodies that bind the asp-hemolysin" (*id.* at 14).

Appellant does not argue the claims subject to this ground of rejection separately. We select claim 23 as representative of the rejected claims. *See* 37 C.F.R. § 41.37(c)(1)(vii).

In view of the positions advanced by Appellant and the Examiner, the issue with respect to this rejection is whether Appellant has shown that the Examiner erred in concluding that the process recited in claim 23 would have been obvious to one of ordinary skill viewing the teachings of Sakaguchi and Harlow.

FINDINGS OF FACT ("FF")

1. Sakaguchi "describe[s] the results of an experiment to determine whether or not hemolysin production occurs in mice when infected experimentally with Aspergillus, whether or not the toxin promoted the experimental infection, and whether diffusion or obstruction occurred in various organs and tissues" (Sakaguchi 3). [6]

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[5] Reply Brief entered January 16, 2007.
[6] Page numbers refer to those in the translation entered June 19, 2003.

2. Sakaguchi discloses that viable spores of *Aspergillus fumigatus* were intravenously inoculated into mice (*id.* at 2 (abstract)).

3. Sakaguchi discloses that "viable organisms were detected in the kidney and brain ten days after challenge and secretion of Asp-hemolysin from the mycelia was actually observed immunohistochemically in the tissues using a technique of indirect enzyme labeled antibody (peroxidase binding IgG antibody)" (*id.*).

4. Harlow discloses that, when detecting substances of interest in fixed cells or tissues, "the antibodies can be labeled directly or they can be detected by using a labeled secondary reagent that will bind specifically to the primary antibody. Both the direct and indirect detection methods are in common use" (Harlow 390).

5. Harlow discloses that, while it has certain disadvantages, "[i]n general, direct labeling of the primary antibody will produce cleaner signals with lower background." (*Id.*)

PRINCIPLES OF LAW

In *KSR Int' l Co. v. Teleflex Inc.*, 550 U.S. 398, 415 (2007), the Supreme Court rejected a "rigid approach" to the obviousness question, and instead emphasized that "[t]hroughout this Court's engagement with the question of obviousness, our cases have set forth an expansive and flexible approach . . . ."

The Court thus reasoned that the analysis under 35 U.S.C. § 103 "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *Id.* at 418; *see*

also id. at 421 ("A person of ordinary skill is . . . a person of ordinary creativity, not an automaton.").

During examination the PTO must interpret claims using "the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the applicant's specification." *In re Morris*, 127 F.3d 1048, 1054 (Fed. Cir. 1997).

Moreover, "[i]f the claim preamble, when read in the context of the entire claim, recites limitations of the claim, or, if the claim preamble is 'necessary to give life, meaning, and vitality' to the claim, then the claim preamble should be construed as if in the balance of the claim." *Pitney Bowes, Inc. v. Hewlett Packard Co.*, 182 F.3d 1298, 1305 (Fed. Cir. 1999).

On the other hand:

> If . . . the body of the claim fully and intrinsically sets forth the complete invention, including all of its limitations, and the preamble offers no distinct definition of any of the claimed invention's limitations, but rather merely states, for example, the purpose or intended use of the invention, then the preamble is of no significance to claim construction because it cannot be said to constitute or explain a claim limitation.

Id.

ANALYSIS

Appellant's arguments do not persuade us that the Examiner erred in concluding that claim 23 encompasses a process that an ordinary artisan would have considered obvious in view of Sakaguchi and Harlow.

Claim 23 recites a method "for determining *if* an animal has been exposed to a specific hemolysin-producing fungus" (emphasis added). The

determination is made by performing the claimed steps of (a) contacting a sample from the animal with labeled hemolysin-binding antibodies, and (b) detecting any complex formed between the labeled antibodies and the hemolysin.

We agree with Appellant that, giving claim 23 its broadest reasonable interpretation, the preamble statement that the method determines "if an animal has been exposed" to a hemolysin-producing fungus does not encompass processes in which steps (a) and (b) are performed on a subject that was deliberately infected with the fungus.

We acknowledge that a practitioner might want to verify the degree of infection in a subject that is known to have been exposed. We do not agree, however, that it is reasonable to interpret claim 23 as encompassing such a process.

The preamble explicitly states that the purpose of performing the claimed steps is to determine "if" a subject has been exposed to a particular class of fungi. If the claim were interpreted as encompassing processes where the subject's exposure status was already known, there would be no reason to perform the claimed steps. Because the preamble and body of the claim are tied together in this manner, we do not agree that it is reasonable to interpret claim 23 as encompassing a process in which steps (a) and (b) are performed on a subject that was deliberately infected with the fungus.

Even with this claim interpretation, however, Appellant's arguments do not persuade us that the Examiner erred in concluding that Sakaguchi would have suggested the process recited in claim 23 to an ordinary artisan.

We acknowledge that Sakaguchi's article is a report on the extent and symptoms of a deliberately caused *A. fumigatus* infection (FF 1), which as

stated above, is not encompassed by claim 23. However, the obviousness analysis is not limited to the explicit disclosures in prior art publications, but must also take account of what an ordinary artisan would reasonably infer from those disclosures. *KSR*, 550 U.S. at 418.

In the instant case, Sakaguchi explicitly discloses that the *A. fumigatus* hemolysin, or Asp-hemolysin, can be detected in tissue samples from exposed animals using antibodies (FF 3). Given that disclosure, an ordinary artisan would have reasonably inferred that applying Sakaguchi's antibody detection methodology to samples from other animals would be useful for determining if the animal had been exposed to *A. fumigatus*. Thus, while it may be true that Sakaguchi does not explicitly describe a process of determining whether an animal has been exposed to a hemolysin-producing fungus, Sakaguchi amply suggests such a process, in our view.

We also acknowledge that Sakaguchi does not explicitly state that the Asp-hemolysin is species-specific to *A. fumigatus*. As Appellant concedes, however, "it is inherent that the hemolysins are unique if one is able to identify different strains of fungi, which is one object of the present invention" (App. Br. 8).

While it is true that the rationale for a prima facie case of obviousness cannot be based on an undisclosed inherent prior art property, in the instant case the conclusion of obviousness is not based on whether Sakaguchi's hemolysin is species-specific. Rather, the rationale for practicing the claimed process is based on the recognition from Sakaguchi that the hemolysin from *A. fumigatus* can be detected in tissue samples from exposed animals using antibodies.

As Appellant's arguments do not persuade us that the Examiner erred in concluding that claim 23 would have been obvious to an ordinary artisan in view of Sakaguchi and Harlow, we affirm the Examiner's rejection of claim 23 over those references. Claims 25-29 fall with claim 23 as they were not argued separately. *See* 37 C.F.R. § 41.37(c)(1)(vii).

ANTICIPATION

Claim 33 stands rejected under 35 U.S.C. § 102(b) as anticipated by Sakaguchi (Ans. 5-7).

Appellant contends that the Examiner's finding of anticipation is erroneous because claim 33 is directed to determining *if* an animal has been exposed to specific hemolysin-producing fungus, whereas Sakaguchi "knew that the animals had been exposed to *A. fumigatus* because the researchers had infected the animals with *A. fumigatus* and monitored the progress of the infection" (App. Br. 10).

The Examiner responds that claim 33 recites a single method step which is described in Sakaguchi (Ans. 16-17). Thus the Examiner argues, the "claims require detection of exposure, the fact that the exposure [in Sakaguchi] was deliberate does not obviate the fact that exposure to a hemolysin fungus was detected by detection of hemolysin in tissue samples" (*id.* at 17).

Appellant has the better position. Claim 33 recites a "method for determining *if* an animal has been exposed to a specific hemolysin-producing fungus" (emphasis added). The determination is made by detecting the presence of the hemolysin in a sample from the animal.

Similar to the discussion above regarding claim 23, we do not agree with the Examiner that it is reasonable to interpret claim 33 as encompassing

processes, like Sakaguchi's, in which the detecting step is performed on a subject that has been deliberately infected with the fungus. If the claim were interpreted as encompassing processes where the subject's exposure status was already known, there would be no reason to perform the claimed steps.

Thus, because the Examiner's anticipation rejection is not based on a reasonable interpretation of claim 33, we reverse it.

WRITTEN DESCRIPTION -- CLAIMS 23-29 AND 33

ISSUE

Claims 23-29 and 33 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement (Ans. 7). For reasons unclear, the Examiner also made a separate written description rejection of claims 23-26 based essentially on the same rationale (*id.* at 9-10). As these rejections are cumulative, we consider them together.

The Examiner contends that the recitation in the claims of determining whether an animal has been exposed to "a specific hemolysin-producing fungus" encompasses determining whether the animal has been exposed to a particular species of fungus, that is, that the exposure-detecting method is "species specific" (Ans. 7).

In contrast, the Examiner argues, "Appellant has not pointed to the specification by page and line number where written description support for this claim language can be found. Further, the there is no conception or written description of any hemolysin being species-specific" (*id.*). Moreover, the Examiner urges, "there is no comparison of hemolysins of different Fungal genera, much less any discussion of different species within the same genera nor the ability of any antibody to discriminate between them" (*id.*).

Appellant contends that paragraphs [0012] and [0015] of the Specification disclose that the invention's objectives include providing methods of screening animals for exposure to hemolysin-producing fungi and for identifying strains of such fungi (App. Br. 11). Appellant contends that if "the hemolysins were not species-specific, the present application would be inoperable, as it is the specific hemolysins that make it possible to identify different species of fungi" (*id.*).

Appellant further contends that, as stated in paragraph [0034], the claimed test allows a practitioner "to identify the source of the hemolysin in a human or other animal that has been exposed to such a fungus. Unless the hemolysin is specific for each hemolysin-producing fungus, this assay would be worthless other than for a determination that the infection was from a hemolysin-producing fungus" (Reply Br. 4).

Appellant further contends that, "[w]hile it has not been recited in the specification in the same manner as claims 23-26 are worded, it is clear that one skilled in the art would appreciate that hemolysin-producing fungi produce species-specific hemolysins" (App. Br. 14). Thus, Appellant urges, a skilled artisan reading the Specification would have recognized "that hemolysin-producing fungi produce hemolysin that is species specific, so that individual fungi can be identified. It is respectfully submitted that the recitation of 'species-specific hemolysin' is not new matter, but is an inherent property of the hemolysin produced by hemolysin producing fungi" (*id.* at 15).

Appellant does not argue any of the claims subject to these rejections separately. We select claim 23 as representative of the rejected claims. *See* 37 C.F.R. § 41.37(c)(1)(vii).

Thus, in view of the positions advanced by Appellant and the Examiner, the issue with respect to these rejections is whether Appellant has shown that the Examiner erred in finding that the Specification does not provide adequate descriptive support for the language in claim 23 requiring the practitioner to determine "if an animal has been exposed to a specific hemolysin-producing fungus, which hemolysin is species-specific."

FINDINGS OF FACT

6. The Specification states that "[i]t is an object of the present invention to provide a method and reagent for screening humans and other animals for exposure to hemolysin-producing fungi. . . .

It is a further object of the present invention to identify strains of fungi using an *in vitro* test" (Spec. [0012]-[0015]).

7. The Specification states:

> The present inventor has discovered a method for purifying fungal hemolysin proteins so that these hemolysin proteins can be used to demonstrate exposure to fungi for environmental or medical evaluations, as well as to prepare vaccines against fungal infection and to produce anti-bacterial and anti-fungal compositions. These fungal hemolysin proteins may be present in the blood, urine, saliva, or other measurable body fluid or material of a human or animal infected with the fungi. Antibodies produced by any appropriate technique, such as in rabbits, or monoclonal antibodies, against the hemolysin protein are used to assay for these proteins. The assay itself can be of any conventional immunoassay type, such as ELISA, RIA, etc.

(*Id.* at [0021].)

8. The Specification discloses that "[b]y growing strains of hemolysin producing fungi *in vitro* and isolating the hemolysin, it is now possible to

use the protein obtained to identify fungi which are isolated from buildings, homes, schools, and the like" (*id.* at [0024]).

9. The Specification discloses a process in which conidia of the fungus *Stachybotrys chartarum* were cultured, and the hemolysin produced by the fungus was obtained from fractionated culture medium (*id.* at [0025]-[0027]).

Rabbits were immunized with the hemolysin, and anti-hemolysin antibodies from the immunized rabbits were affinity purified using immobilized hemolysin (*id.* at [0030]).

The capacity of the purified antibodies to bind to the hemolysin was verified in an ELISA in which the hemolysin peptide was coated onto microliter wells, and then contacted with the anti-hemolysin antibodies and a second detecting antibody (*id.* at [0031]).

10. The Specification discloses:

> These antibodies to fungal hemolysin can be used in a conventional immunoassay such as an ELISA to determine if one has been exposed to strains of fungi which produce hemolysin. The hemolysin protein itself can be used to determine if one has produced antibodies in response to exposure to the fungus.

(*Id.* at [0032] (as amended January 11, 2002).)

11. The Specification discloses:

> The present invention thus provides a method to determine if a human or other animal has been exposed to a hemolysin-producing fungus such as *Stacybotrys chartarum*. By assaying samples from a human or other animal for antibodies to a hemolysin-producing fungus, it is now possible to determine if the human or other animal has been exposed to such a fungus.

(*Id.* at [0033].)

12. The Specification discloses:

> Exposure to low levels of hemolysins can lead to potassium ion depletion in monocytes, which can lead to activation of interleukin-converting enzyme. This in turn can lead to rapid and massive release of mature IL-beta. In addition, T-lymphocytes that leak potassium ions undergo programmed cell death (apoptosis)[.] For this reason, it is critical to identify the source of the hemolysin in a human or other animal which may have been exposed to a hemolysin-producing fungus and immediately begin appropriate treatment.

(*Id.* at [0034].)

13. The Specification discloses that "[t]he method of the present invention is useful for assaying for exposure to or for the presence of any hemolysin-producing fungal strain. Some nonlimiting examples of these fungal strains are *Stacybotrys chartarum, Aspergillus fumigasus, Candida albicans* and *Penicillium chysogenum*" (*id.* at [0035]).

PRINCIPLES OF LAW

As stated in *TurboCare Div. of Demag Delaval Turbomachinery Corp. v. General Elec. Co.*, 264 F.3d 1111, 1118 (Fed. Cir. 2001):

> The written description requirement and its corollary, the new matter prohibition of 35 U.S.C. § 132, both serve to ensure that the patent applicant was in full possession of the claimed subject matter on the application filing date. When the applicant adds a claim or otherwise amends his specification after the original filing date . . ., the new claims or other added material must find support in the original specification.

The test for determining whether a specification is sufficient to support a particular claim "is whether the disclosure of the application relied upon 'reasonably conveys to the artisan that the inventor had possession at

that time of the later claimed subject matter.'" *Ralston Purina Co. v. Far-Mar-Co, Inc.,* 772 F.2d 1570, 1575 (Fed. Cir. 1985) (quoting *In re Kaslow,* 707 F.2d 1366, 1375 (Fed. Cir. 1983)).

Thus, "[i]t is not necessary that the application describe the claim limitations exactly, but only so clearly that persons of ordinary skill in the art will recognize from the disclosure that appellants invented processes including those limitations." *In re Wertheim*, 541 F.2d 257, 262 (CCPA 1976) (citation omitted); *see also Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1323 (Fed. Cir. 2000) ("In order to satisfy the written description requirement, the disclosure as originally filed does not have to provide *in haec verba* support for the claimed subject matter at issue.").

ANALYSIS

Appellant's arguments do not persuade us that the Examiner erred in finding that claim 23 lacks adequate descriptive support in the Specification.

Claim 23 recites "[a] method for determining if an animal has been exposed to a specific hemolysin-producing fungus, which hemolysin is species-specific." Like Appellant and the Examiner, we interpret this language as requiring the practitioner to determine which particular species of hemolysin-producing fungus the animal has been exposed to.

In contrast to this requirement, we are convinced that the Specification would have conveyed to a skilled artisan that Appellant invented a less specialized method, which merely allows the practitioner to determine whether an animal has been exposed to hemolysin-producing fungi in general, without any distinction between species.

For example, the Specification discloses the preparation of antibodies to only a single hemolysin, the one produced by the fungus *Stachybotrys*

chartarum (FF 9). The Specification does not state that the hemolysin is specific to that species of fungus. The Specification does not state that the purified antibodies to that hemolysin would be incapable of detecting hemolysins from other species of fungi.

To the contrary, the Specification explicitly states that "[t]hese antibodies to fungal hemolysin can be used in a conventional immunoassay such as an ELISA to determine if one has been exposed to strains of fungi which produce hemolysin" (Spec. [0032]). Thus, rather than suggesting that the only antibodies actually prepared by Appellant were specific to *S. chartarum*, the Specification states, more generally, that those antibodies would be useful in determining if a subject had been exposed to hemolysin-producing fungal strains. Thus, the Specification suggests a generic applicability for the disclosed antibodies, rather than a species-specific one.

We acknowledge the Specification's stated objectives of "screening humans and other animals for exposure to hemolysin-producing fungi" (Spec. [0012]), and "identify[ing] strains of fungi using an *in vitro* test" (*id.* at [0015]).

Without any specific disclosure about these methods' capacities to distinguish between different species of fungi, however, it is not clear that the Specification contemplated anything more than the general ability to detect hemolysin-producing fungi, as opposed to distinguishing between species. This is particularly true given the Specification's suggestion that the antibodies to *S. chartarum* would be useful in detecting a plurality of hemolysin-producing strains (*id.* at [0032]).

We also acknowledge that the Specification's disclosure that "it is critical to identify the source of the hemolysin in a human or other animal which may have been exposed to a hemolysin-producing fungus and immediately begin appropriate treatment" (*id.* at [0034]). However, Appellant points to no disclosure in the Specification, or other evidence of record, suggesting that treatment for infection by one species of hemolysin-producing fungus would be different than treatment for infection by different fungal species.

Moreover, the next paragraph of the Specification states that "[t]he method of the present invention is useful for assaying for exposure to or for the presence of *any* hemolysin-producing fungal strain. Some nonlimiting examples of these fungal strains are *Stacybotrys chartarum*, *Aspergillus fumigasus*, *Candida albicans* and *Penicillium chysogenum*" (*id.* at [0035]) (emphasis added).

Given Appellant's inability to point to a specific statement in the Specification that the disclosed methods differentiate between different fungal species, and the suggestion that the *S. chartarum* antibodies can be used to detect hemolysins from other "strains" (*id.* at [0035]) and are therefore *not* species-specific, we are convinced that the disclosure of detecting "any hemolysin-producing fungal strain" (*id.* at [0035]), would not have conveyed to a skilled artisan that Appellant invented a method that allowed a practitioner to determine which particular species of hemolysin-producing fungus the animal has been exposed to.

Appellant argues that, "[u]nless the hemolysin is specific for each hemolysin-producing fungus, this assay would be worthless other than for a determination that the infection was from a hemolysin-producing fungus,"

and that the Specification therefore would have conveyed to a skilled artisan that Appellant invented a species-specific identification method (Reply Br. 4). This argument does not persuade us, however, that the Examiner erred in finding a lack descriptive support for claim 23.

We acknowledge that the Specification must be viewed with the understanding of a person of ordinary skill in the art. *See, e.g., In re Wertheim*, 541 F.2d at 262.

Nonetheless, for the reasons discussed above, we are not convinced that any of the portions of the Specification cited by Appellant, or related sections, would have conveyed to a skilled artisan that Appellant invented anything beyond a generalized method that merely allows the practitioner to determine whether an animal has been exposed to hemolysin-producing fungi, without any distinction between species. The fact that a skilled artisan might have found the disclosed methods useful for purposes beyond the Specification's explicit disclosure does not demonstrate that the Specification contemplated those further uses as part of the invention.

As Appellant's arguments do not persuade us of error in the Examiner's finding of lack of written description with respect to claim 23, we affirm both of the Examiner's rejections of that claim under 35 U.S.C. § 112, first paragraph. As claims 24-29 and 33 were not argued separately, they fall with claim 23. *See* 37 C.F.R. § 41.37(c)(1)(vii).

WRITTEN DESCRIPTION -- CLAIMS 30-32

ISSUE

Claims 30-32 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement (Ans. 7-8). The Examiner finds that, in contrast to claim 30, the portions of the Specification

relating to screening buildings for hemolysin-producing fungi "do not provide for the concept of contacting a building sample with a labeled antibody to detect the hemolysin" (Ans. 8).

Appellant contends that a skilled artisan would have known how to collect a representative sample from a building, and would also have recognized that fungal cultures obtained from that sample "could be assayed in the same manner as samples from bodily fluids" (App. Br. 12). Thus Appellant argues, a skilled artisan "does not need to have each step spelled out in excruciating detail, as one skilled in the art can readily ascertain how to obtain suitable samples and proceed with such an assay" (*id.* at 12-13).

Appellant does not argue any of the claims subject to these rejections separately. We select claim 30 as representative of the rejected claims. *See* 37 C.F.R. § 41.37(c)(1)(vii).

In view of the positions advanced by Appellant and the Examiner, the issue with respect to this rejection is whether the Examiner erred in finding that the Specification fails to provide adequate descriptive support for the method in claim 30, which requires contacting a sample obtained from a building "with labeled antibodies which bind to the fungal hemolysin or to active fragments of the fungal hemolysin . . . and . . . detecting any complex formed between the labeled antibodies and the fungal hemolysin or active fragments thereof" that might be present in the sample.

FINDINGS OF FACT

14. The Specification discloses:

> Many fungi are present in buildings such as offices, homes, schools, warehouses, etc., but not all fungi adversely affect humans. To determine if a building holds fungi which are problematic, *i.e.*, produce hemolysin, a strain of a fungus

> obtained from the building is grown in a synthetic medium such as tryptic soy broth at a temperature at which the fungus can be made to grow, generally about 37°C. The culture filtrate is then applied to a plate, such as a 5% sheep red blood cell blood agar plate. If the filtrate is shown to be hemolytic, the strain is problematic and may pose a health risk.
>
> Once a building has been found to contain problematic fungi, the building is treated to remove or destroy the fungi. The screening can then be repeated to ensure that the problematic fungi have been eliminated from the site.

(Spec. [0036]-[0037].)

ANALYSIS

Appellant's arguments do not persuade us that the Examiner erred in finding that claim 30 lacks adequate descriptive support in the Specification.

Claim 30 recites a method for determining if a building contains a hemolysin-producing fungus. The determination is made by performing the steps of (a) obtaining a sample from the building, (b) obtaining hemolysin from the sample if hemolysin-producing fungi are present in the sample, (c) contacting the sample with labeled antibodies which bind to the hemolysin or active fragments of hemolysin, and (d) detecting any complex formed between the labeled antibodies and the fungal hemolysin or active fragments thereof.

As Appellant points out, paragraphs [0036] and [0037] describe the process by which a sample from a building is testing for contamination by hemolysin-producing fungi. As the Examiner points out, however, that disclosure makes no mention of contacting the culture with anti-hemolysin antibodies. Rather, the hemolysis evidenced by the blood cell agar provides the indication that the culture contains hemolysins.

Appellant does not point to any disclosure in the Specification that links the building sample assay methods to the antibody-based detection methods used for assaying animal samples. Rather, an overall reading of the portions of the Specification cited above (FF 6-14) shows that the building sample assays and animal sample assays are distinct and separate embodiments.

Thus, while it may be true that Appellant possessed the component parts of the process recited in claim 30 in separate and distinct embodiments, we are not convinced that the Specification would have conveyed to a skilled artisan that Appellant actually invented a process that used those components *in combination*, in the manner recited in claim 30. We therefore affirm the Examiner's written description rejection of claim 30 under 35 U.S.C § 112, first paragraph.

Because they were not argued separately, claims 31 and 32 fall with claim 30.

ENABLEMENT -- CLAIMS 30-32

ISSUE

Claims 30-32 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement (Ans. 8-9). The Examiner contends that the Specification does not disclose whether hemolysins are "readily available on the spore or conidia coat" or whether "the presence of fungal-hemolysin can be detected in a crude building sample in the absence of broth culture" (*id.* at 9).

Thus, the Examiner argues, an ordinary artisan "would have to determine if the hemolysin was present on the surface of the fungal spores or conidia before any assessment of the presence or absence in a building

sample could begin" (*id.*). Further, the Examiner argues, "even if the spore surface had the hemolysin present, it is unclear if the method as claim is sensitive enough to detect the levels present in a crude building sample" (*id.*).

Appellant contends that "[o]ne skilled in the art of clinical assays or assaying for deleterious microorganisms in a building or other such environment, could read the present specification and readily contrive to conduct such assay without undue experimentation" (App. Br. 13). Specifically, Appellant argues, an ordinary artisan would know how to "obtain samples from a building or other environment, and then, as described at paragraphs 25 to 32, assay for the presence of fungal hemolysins in the sample. Paragraph 36, which pertains specifically to screening fungi in a building, even discloses the culturing technique for growing the suspected hemolysin-producing fungi" (*id.*).

In view of the positions advanced by Appellant and the Examiner, the issue with respect to this rejection is whether Appellant has shown that the Examiner erred in concluding that an ordinary artisan viewing the present Specification would have had to resort to undue experimentation to practice the process recited in claims 30-32.

PRINCIPLES OF LAW

As noted in *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313 (Fed. Cir. 2003):

> The enablement requirement is often more indulgent than the written description requirement. The specification need not explicitly teach those in the art to make and use the invention; the requirement is satisfied if, *given what they already know*, the specification teaches those in the art enough

> that they can make and use the invention without "undue experimentation."

Id. at 1334 (emphasis added).

Thus, "[working] examples are not required to satisfy section 112, first paragraph." *In re Strahilevitz*, 668 F.2d 1229, 1232 (CCPA 1982). For example, in *Falko-Gunter Falkner v. Inglis*, 448 F.3d 1357, 1365 (Fed. Cir. 2006) the court affirmed this Board's conclusion that claims to a modified pox virus vaccine were enabled, despite the fact that the specification focused on viruses other than pox virus, provided no examples directed to pox virus, and discussed pox virus only in general terms relating to the inventive disclosure.

ANALYSIS

We agree with Appellant that the Examiner erred in concluding that the Specification fails to enable claims 30-32.

As noted above, claim 30 recites a method for determining if a building contains a hemolysin-producing fungus. The determination is made by performing the steps of (a) obtaining a sample from the building, (b) obtaining hemolysin from the sample if hemolysin-producing fungi are present in the sample, (c) contacting the sample with labeled antibodies which bind to the hemolysin or active fragments of hemolysin, and (d) detecting any complex formed between the labeled antibodies and the fungal hemolysin or active fragments thereof.

As also noted above in the discussion regarding the written description rejection over these same claims, we agree with Appellant that the component parts of the assay recited in claim 30 are disclosed in the Specification, albeit not in a manner sufficient to provide adequate

descriptive support. However, as stated in *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d at 1334, "[t]he enablement requirement is often more indulgent than the written description requirement."

We conclude that to be the case here. The Specification discloses the collection of samples from buildings (FF 14), and also discloses methods by which hemolysin can be obtained from collected samples by culturing the fungi and getting the hemolysin from the culture supernatant (FF 9). We are therefore not persuaded that an ordinary artisan would have had to experiment unduly to practice the process recited in claim 30.

The Examiner's issue appears to be that the claim recites obtaining hemolysin from the building sample, whereas the only methods described in the Specification for obtaining hemolysin from animal or building samples involves culturing the fungi obtained from the sample (*see* Ans. 26; *see also* FF 9 (culturing *S. chartarum* conidia to obtain hemolysin in culture filtrate) and FF 14 (culturing fungi obtained from building sample)).

Thus, the Examiner argues, the "antecedent basis of the claim does not provide for intermediate strain isolation and culturing steps. The hemolysin must be obtained from the sample from the building. The strain isolation and culturing technique is not set forth in the claims" (Ans. 27).

We are not persuaded. While claim 30 may lack the precise wording preferred by the Examiner, we see nothing that precludes the obtaining step from involving culturing the collected fungi to obtain the hemolysin. While this might mean that step (c) requires contacting a cultured sample with labeled antibodies, we do not agree with the Examiner that this is an unreasonable interpretation of claim 30.

As Appellant's arguments persuade us that the Examiner's conclusion of non-enablement with respect to claim 30 is erroneous, we reverse the Examiner's enablement rejection of that claim, and its dependents.

INDEFINITENESS

Claims 30-32 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite (Ans. 10-11). The Examiner finds that the preamble of claim 30 recites a method for determining if a building contains a hemolysin-producing fungus, whereas step (b) recites "'obtaining hemolysin from the sample if hemolysin-producing fungi are present in the sample'" (*id.* at 10).

The Examiner concludes that step (b) requires the practitioner to know that hemolysin is present in the sample, and that step (b) is therefore inconsistent with the preamble, which requires "measuring an unknown, where the presence or absence of a hemolysin is unknown. . . . What is the purpose of performing the assay[?]" (*Id.* at 10-11.)

Appellant contends that step (b) of claim 30 does not require knowledge of whether the sample contains hemolysin. We agree.

"A claim is indefinite if, when read in light of the specification, it does not reasonably apprise those skilled in the art of the scope of the invention." *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d at 1342.

Claim 30 recites a method for determining if a building contains a hemolysin-producing fungus. The steps by which the determination is made include (a) obtaining a sample from the building, (b) "obtaining hemolysin from the sample if hemolysin-producing fungi are present in the sample."

At the outset, we note that the Examiner's interpretation of claim 30's preamble as requiring the use of an unknown sample is entirely inconsistent

with the interpretation applied in the art rejections, where the Examiner asserted that the language "determining if" included testing samples whose exposure status was known (*see, e.g.* Ans. 16-17).

As to the claim itself, we do not agree that step (b) requires knowing that hemolysin-fungi are present in the sample. Specifically, if the unknown sample contains hemolysin-producing fungi, then a step of culturing the fungi from the sample would allow the practitioner obtain hemolysin from the sample. Conversely, if the unknown sample does not contain hemolysin-producing fungi, then a step of culturing the fungi from the sample would not allow the practitioner obtain hemolysin from the sample.

Thus, because the language in claim 30 would have apprised an ordinary artisan of the scope of the claim, we reverse the Examiner's rejection of claim 30, and its dependents, as being indefinite.

SUMMARY

We affirm the Examiner's rejection of claims 23 and 25-29 under 35 U.S.C. § 103(a) as obvious in view of Sakaguchi and Harlow.

We reverse the Examiner's rejection of claim 33 under 35 U.S.C. § 102(b) as anticipated by Sakaguchi.

We affirm the Examiner's rejection of claims 23-29 and 33 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

We affirm the Examiner's rejection of claims 30-32 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

We reverse the Examiner's rejection of claims 30-32 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement.

We affirm the Examiner's rejection of claims 23-26 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

We reverse the Examiner's rejection of claims 30-32 under 35 U.S.C. § 112, second paragraph, as being indefinite.

TIME PERIOD

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED-IN-PART

cdc

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